IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE UK LTD. and
VIIV HEALTHCARE CO.,
Plaintiffs,
v.
LUPIN LTD., et al.
Defendants.

C.A. No. 11-cv-00576-RGA
(CONSOLIDATED)

HIGHLY CONFIDENTIAL
FILED UNDER SEAL

PLAINTIFFS' REPLY POST-TRIAL BRIEF ON INFRINGEMENT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Federal Register Notice

Lupin fails to rebut ViiV's showing that Lupin infringes the asserted claims of the '191 patent. ViiV respectfully requests that the Court enter judgment accordingly.

A. Lupin's Generic Contains The Claimed Abacavir (All Claims)

1. "1S…methanol" Includes Salts

Lupin mistakenly argues that its generic product does not meet the "1S … methanol" term because that term does not include salts. ***First***, contrary to Lupin's argument, Dr. Langer did not admit that the claims are limited to "abacavir free base," a term Lupin coined. D.I. 210 (Lupin "Opp. Br.") 2-3. He agreed that "1S … methanol" ***includes*** abacavir "free base." As Dr. Langer made clear, the term includes salts, and abacavir "free base" is contained in abacavir sulfate. *See, e.g.*, Tr. 189:14-22, 239:6-241:11. ***Second***, while Lupin suggests at various points that its construction is legally compelled, it cites no case holding that recitation of an active ingredient cannot cover the salt form, as a matter of patent law.[1] Lupin attempts to distinguish *Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367 (Fed. Cir. 2003) and analogize to *Hoffmann-LaRoche Inc. v. Apotex Inc.*, 2010 WL 1875569 (D.N.J. May 10, 2010) largely based on the way the respective patents organized their specifications, which is irrelevant. Opp. Br. 3-4. The ***relevant*** facts are strikingly similar to *Merck*. In both this case and in *Merck*, the patent specifications state expressly that salts are within the scope of the invention. *Compare* JX 1 3:19-27, *with Merck*, 347 F.3d at 1370-71. Moreover unlike *Roche*, where the claims referred to the

[1] Lupin's reliance on a proposed FDA rule is irrelevant and improper. Opp. Br. 6 n.4 (citing 54 Fed. Reg. 28,872, 28,878 (July 10, 1989)). In that document, FDA specifically disclaims any expertise or responsibility to construe patent claims. 54 Fed. Reg. at 28,888 ("Determinations concerning the scope of patents are the province of the [PTO] and of the courts. FDA does not have the expertise…."). *Actavis Elizabeth LLC v. FDA*, 689 F. Supp. 2d 174 (D.D.C. 2010), *aff'd*, 625 F.3d 760 (D.C. Cir. 2010) further undermines Lupin's argument, indicating that the FDA does ***not*** view salts of previously approved molecules as "new chemical entit[ies]." *Id.* at 178. More importantly, the proposed rule was not in evidence, nor mentioned by any witness at trial. The only mention of FDA views was Lupin's counsel's unsolicited, unsworn testimony at closing, Tr. (Ms. Mazzochi) 1522:14-18, which is not evidence, not relevant, and not correct.

acid form of the chemical ***as an "acid,"*** the claims here do not refer to "***free base***." It is irrelevant that the *Roche* claims referred to "physiologically active ***salt***," as the term "physiologically functional derivative" in this case is far broader than salts of the active ingredients, Opp. Br. 4 n.2, and therefore neither "redundant" nor "unnecessary." *Id.* at 4.

Lupin does not dispute that "physiologically functional derivative" is broader than salts, nor that the structure of the independent and dependent claims show that the abacavir limitation includes salts (*e.g.*, claims 7, 35, 40, 42). Thus, that claim 49 specifies the succinate salt as a physiologically functional derivative consistent with the broad scope of that term is beside the point.[2] *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006) is irrelevant, as this case does not present an issue of improper narrowing and broadening of dependent claims under § 112(d). Finally, because the asserted claims cover salts, *Lucent* is not implicated. Opp. Br. 5.

2. Lupin's Generic Product Contains Abacavir, Even Under Lupin's Reading of the "1S … methanol" Term

No one disputes that Lupin's generic product contains abacavir sulfate. Lupin is incorrect, however, to argue from that premise that its product does not contain the claimed abacavir (and to assert that the claims do not cover Trizivir®). *See* Opp. Br. 2 n.1. Even under Lupin's reading of the claims as limited to "abacavir free base," Lupin's product infringes.

Lupin focuses on the fact that its ANDA "defines" or "list[s]" "abacavir sulfate" as the active ingredient, Opp. Br. 6-7, and that abacavir sulfate has a different molecular weight and better tablet stability than "abacavir free base." *Id.* at 8-9. None of that detracts from the fact that both sides' experts, Lupin's representatives, and Lupin's ANDA confirm that Lupin's product contains abacavir, and delivers abacavir to patients. That is sufficient for infringement.

ViiV's expert Dr. Langer testified that abacavir sulfate in Lupin's generic product

[2] Also irrelevant is the fact that claim 40 is an inadvertent duplication of claim 35. Opp. Br. 5-6.

contains abacavir: "when you have abacavir sulfate, you have both abacavir and you have abacavir sulfate. In other words, ***abacavir is in abacavir sulfate***. And it's not just me saying that … Lupin's ANDA says that." Tr. 189:14-22; *see also* Tr. 239:6-241:11; LTX 1465 at 000490. Dr. Langer is correct—Lupin's ANDA states repeatedly that Lupin's generic product contains abacavir. D.I. 203 ("ViiV Br.") 7-8 (collecting citations). Lupin accuses ViiV of "artificially cropp[ing] quotes to support its position," Opp. Br. 7, but even the "exclude[d]" language Lupin quotes, *id.* at 8 n.5, further confirms Dr. Langer's testimony. For instance, Lupin quotes its ANDA as stating "abacavir sulfate … is one of multiple products ***containing abacavir***," and adds that its label "explains the dosage form ***contains*** '300 mg ***of abacavir*** as abacavir sulfate.'" *Id.* at 8 n.5 (quoting PTX 135 at 000003; PTX152 at 012341).

Lupin's expert Dr. Arnold further confirmed that Lupin's tablet "eventually provides ***abacavir***. ***That is the active ingredient***. ***Otherwise, the product wouldn't work***." Tr. 280:13-19. Indeed, Lupin's argument that carbovir triphosphate is the actual compound inhibiting HIV replication, Opp. Br. 9, further confirms that Lupin's generic product contains abacavir, because carbovir triphosphate is the result of cellular conversion ***of abacavir***. PTX 152 at 012361.

Against the evidence at trial, Lupin attacks a strawman, asserting that ViiV maintains that abacavir will only exist *in vivo*, when the tablet and abacavir sulfate are both "destroyed." Opp. Br. 9. ViiV's position is and always has been, however, that Lupin's generic product contains abacavir. *See, e.g.*, ViiV 4/30/2012 Inf. Contentions 4-5, App. A 51-52, 65, 77, 88 (Ex. A).[3] And it is undisputed that the generic product will provide abacavir when administered. Lupin's assertion that "no claim calls for a formulation to 'release,' 'provide,' or 'produce,' abacavir,"

[3] For that reason, Lupin's argument that ViiV's infringement case "hinges on a new … theory" is false. Opp. Br. 2. In any event, Lupin did not and could not object to Dr. Langer's testimony at trial on this subject because it fell squarely within his infringement expert report.

Opp. Br. 9, fundamentally misreads the claims and disregards the perspective of a POSA. Claim 47 recites "A ***pharmaceutical*** formulation ***comprising***" the active ingredients. The method claims are even more explicit on this point: all refer to "treating" patients "***with a therapeutically effective amount of*** a combination comprising" the active ingredients, including abacavir. Lupin ultimately admits that its product contains and releases abacavir precisely because it contains abacavir sulfate. Opp. Br. 7 (admitting abacavir can be "derive[d]" from abacavir sulfate); *see also* PTX 152 at 012356 ("In vivo, abacavir sulfate dissociates to its free base, abacavir."). Lupin's expert admits that Lupin's generic product "***provides*** abacavir," Tr. (Arnold) 280:13-19, and a patient taking it is necessarily treated with a therapeutically effective amount of abacavir. Lupin cites nothing suggesting that the abacavir contained in and provided by its product is fundamentally or materially changed as a result of its sulfate form; it is not.

3. Lupin Plainly Infringes Under The Doctrine of Equivalents

To the extent it does not literally infringe, Lupin's use of abacavir sulfate—the same chemical found in Trizivir®—clearly infringes under the doctrine of equivalents. The applicable standard is whether there are "insubstantial differences" between each claim element and the accused product; that standard is met where the accused product performs substantially the same function in substantially the same way, to achieve substantially the same result. ViiV Br. 11-12 (citing *Warner-Jenkinson v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (1997)). The standard is readily satisfied here and Lupin's arguments to the contrary are unavailing, particularly given its failure to present any equivalence evidence at trial.

Lupin argues that "the compound inhibiting HIV replication is carbovir triphosphate—not the free base." Opp. Br. 9. That does not distinguish "abacavir sulfate" from "abacavir free base" because abacavir sulfate contains and provides abacavir, which in turn provides the active metabolite carbovir triphosphate. In response, Dr. Arnold offered no equivalence analysis and

admitted that Lupin's tablet "provides ***abacavir***."[4] Tr. 280:13-19. Lupin asserts that "a salt's function in a tablet is to impart greater stability and handling properties." Opp. Br. 9-10. But that is immaterial as there was no dispute at trial that the ***function*** of "abacavir sulfate" in Lupin's product is to deliver "abacavir" to patients to inhibit HIV replication. Lupin's ANDA referred to "abacavir as abacavir sulfate," not "abacavir sulfate as an inactive ingredient for stability and handling." Again, as Dr. Arnold testified, without abacavir, "the product wouldn't work." Tr. 280:13-19.

As just described, "abacavir sulfate" is insubstantially different from the claimed abacavir under *Warner-Jenkinson*. Lupin's "vitiation" argument—that the term cannot cover abacavir sulfate or the abacavir contained within abacavir sulfate—is merely a flat denial of ViiV's proof, and a repackaging of its literal noninfringement argument. Opp. Br. 10.

Lupin overreaches by arguing that salts were dedicated to the public. *Id.* 10-11. The public dedication doctrine concerns equivalents disclosed but not claimed ***anywhere*** in the patent. *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054-55 (Fed. Cir. 2002). The purpose is to prevent the patentee from drafting and obtaining narrow claims from the Patent Office and then attempting to broaden their scope in litigation through the doctrine of equivalents. *See Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1108 (Fed. Cir. 1996). Even Lupin concedes that, at the very least, other claims in the patent cover salts. Opp. Br. 11.[5] Abacavir sulfate is *claimed in the patent*, and thus in no sense "dedicated to the public." In any event, as described above, the claims asserted here ***do*** cover abacavir sulfate.

Lupin incorrectly argues the method claims "do not cover what is delivered or provided

[4] All emphasis is added unless otherwise indicated.

[5] *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2006) (cited Opp. Br. 11), is not to the contrary. The subject matter dedicated to the public in *Abbott* was not claimed anywhere in the asserted patent. *Id.* at 1297.

to patients *in vivo*." Opp. Br. 11. The claims call for, and Lupin's generic product is designed to provide, "therapeutically-effective amount[s]" of the claimed combinations. JX 1 cls. 20, 32; PTX 152 at 012373. [redacted] Lupin's reliance on *Schering* is unavailing and fails to account for the analogous decision in *Merck*, 347 F.3d at 1371 ("The evidence of all the qualified witnesses was that persons in this field would understand that the acid is the active agent and that ***the acid is administered*** when it is in the form of the salt.").

B. Lupin's Generic Is To Be Used For "Treatment or Prevention of the Symptoms Or Effects" Of HIV Infections (Method Claims)

1. "Treatment or Prevention of the Symptoms or Effects" Includes Inhibiting Replication of HIV

In *Markman* proceedings, Lupin argued that "symptoms or effects of an HIV infection" covered only "opportunistic conditions" and not inhibiting replication of the HIV virus. D.I. 56 at 9-10. ViiV argued that the term had a plain and ordinary meaning, which includes treatment of an HIV infection. *See, e.g.*, Sept. 14, 2012 Tr. 174:7-175:2. The Court rejected Lupin's unduly narrow construction and agreed with ViiV that the plain and ordinary meaning controls. D.I. 126 at 3. Now Lupin ignores that ruling and attempts to resurrect its claim construction dispute as its primary noninfringement argument for the method claims. Opp. Br. 18 (arguing "Lupin's proposed label instructs people how to treat an HIV infection, not the symptoms or effects of an HIV infection"); *id.* at 19 (disputing contributory infringement for the same reason). Lupin's argument is meritless. Lupin's label indicates that the generic product will be used to treat an HIV infection and, therefore, it infringes. ViiV Br. 16, 19-20.

Lupin's generic product will also infringe because it treats and prevents other symptoms or effects of an HIV infection. Lupin has never disputed that one "effect" of an HIV infection is ***replication of the virus***. *See, e.g.*, Opp. Br. 15 (explaining Fischl shows the three drug

combination has "treatment effect on HIV infection to reduce HIV viral load"). Nor has Lupin disputed that the claimed combinations inhibit replication of the virus. In fact, the undisputed evidence shows that Lupin's generic product is indicated to treat that effect, *i.e.*, "by help[ing] lower the amount of HIV in your blood." PTX 152 at 012373; Tr. (Blick) 91:21-94:19.

To attempt to manufacture a dispute, Lupin mischaracterizes Dr. Blick's testimony. For example, Lupin selectively quotes Dr. Blick's testimony as saying he disagreed that treatment of HIV infection falls within the scope of the method claims. Opp. Br. 14 (quoting Tr. 113:22-114:10). In reality, Dr. Blick did not agree with Lupin's counsel's inappropriate attempt to strike language from the claims. Tr. 113:9-115:1. Lupin also argues that Dr. Blick admitted that Lupin's label "nowhere discusses 'symptoms or effects' of an HIV infection." Opp. Br. 17 (quoting Tr. 112:14-19). Again, Dr. Blick admitted only that "that specific ***term*** ['symptoms or effects'] doesn't" appear, but the substance does. Tr. 112:14-19 ("it does refer to lowering HIV in your blood. And that's definitely an ***effect*** of the treatment of the HIV.").

Essentially, Lupin's argument would read "***prevention***" out of the method claims, limit "symptoms or effects" to "opportunistic conditions," and require "direct" treatment as follows:

direct

32. A method for the treatment ~~or prevention~~ of the opportunistic conditions related to ~~symptoms or effects of~~ an HIV infection in an infected animal which comprises treating said animal with a therapeutically effective amount of a combination comprising (1S, 4R)-cis-4-[2-amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol, zidovudine, and (2R, cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one.

Lupin tellingly provides only a cursory response to ViiV's doctrine of equivalents proofs. Opp. Br. 16 & nn.12-13. Lupin ignores that Dr. Langer provided a separate, specific analysis as to why Lupin's products at least meet the treatment element under the doctrine of equivalents. Tr. 198:13-199:1. Dr. Blick corroborated that testimony, explaining that the drugs treat

opportunistic conditions by suppressing HIV viremia and increasing CD4 T helper cells. Tr. 83:12-84:14, 94:3-19. Dr. Arnold admitted that he provided no equivalents analysis, Tr. 287:18-24; and Lupin conceded that increasing CD4 T cells "reflects a consequence of the drugs treating the HIV infection."[6] Opp. Br. 15. Thus, at a minimum, Lupin's generic product will infringe the asserted methods claims under the doctrine of equivalents.

2. Lupin Induces and Contributes to Infringement

ViiV showed that Lupin is liable for indirect (induced and contributory) infringement, ViiV Br. 13-20, and Lupin offers little in response. There is no dispute that Lupin knew about the '191 patent. Tr. (Raghavan) 166:15-167:6, ViiV Br. 19-20; D.I. 178, Ex. 1 ¶¶18-19. Rather, Lupin merely rehashes its "symptoms or effects" argument—*i.e.*, under Lupin's narrow view of "treatment or prevention of the symptoms or effects," the product has substantial noninfringing use for purposes of contributory infringement, and Lupin lacked the requisite intent to induce infringement. Opp. Br. 18, 19. Those arguments are rebutted above and in ViiV's opening brief.

Lupin's label instructs users to perform the patented method and demonstrates Lupin's intent to induce infringement. ViiV Br. 19-20; Tr. (Blick) 94:3-95:4; Tr. (Langer) 201:24-202:21*; see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) ("[I]t is irrelevant that some users may ignore the warnings in the proposed label. The pertinent question is whether the proposed label instructs users to perform the patented method."). Lupin's reliance

[6] Lupin's brief purports to renew objections to Dr. Langer's testimony. Opp. Br. 15 n.10, 16 n.12. The only objection Lupin made when Dr. Langer testified about equivalents was that he was "not qualified to render those opinions in his cumulative status," Tr. 199:2-4, which the Court correctly overruled, Tr. 199:5. Lupin's objection is essentially an admission that Dr. Blick corroborated that testimony. But, in any event, Lupin has waived its *Daubert* attack on Dr. Langer by failing to submit a timely letter to the Court. D.I. 175 at 1, n.1 (requiring submission of letter 24 hours after the transcript is available, or the argument is waived). Further, Lupin's attacks on Dr. Langer's credentials lack merit. Dr. Langer is an Institute Professor at MIT, with considerable experience in pharmaceutical science, drug development and drug formulations, and is qualified to opine as he did. Tr. 174:16-181:24, 182:8; ViiV Br. 5 (qualifications).

on *Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586 (D. Mass. 2005) is misplaced. There, the proposed label ***discouraged*** doctors from prescribing the drugs for treating the claimed purpose. *Id.* at 599. By contrast, Lupin's proposed label ***encourages*** doctors and patients to treat HIV infections and replication, and to treat or prevent opportunistic conditions, and its product has no other use.[7]

C. ViiV Is Entitled To Remedies Including An Order Delaying the Effective Date of Lupin's Approval

Lupin's contention that ViiV is not "entitled to ***any remedy***" for Lupin's infringement is baseless. 35 U.S.C. § 271(e)(4)(A) provides that, upon proof of infringement of a valid patent by an ANDA filing "the court ***shall*** order the effective date of any approval [of the generic] to be a date which is not earlier than the date of expiration of the patent." That remedy is mandatory and nondiscretionary. *See In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367 (Fed. Cir. 2008) ("Subparagraph (A), however, provides an additional type of relief after a finding of infringement under section 271(e)(2) by ***requiring*** the district court to 'order the effective date of any approval of the drug'" to postdate expiration of the patent.).

Separate from, and in addition to, § 271(e)(4)(A), §§ 271(e)(4)(B)-(C) "provide the typical remedies for infringement: injunctive relief and damages." *Id.* at 1367. Those remedies apply if Lupin attempts to or actually launches its generic at risk. *Id.* Lupin incorrectly suggests

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[7] Lupin's two-sentence argument regarding *Commil USA v. Cisco Systems*, 2013 WL 3185535 (Fed. Cir. June 25, 2013) is refuted by *Commil* itself. *Compare* Opp. Br. 18 ("ViiV must also show that Lupin did not have a reasonable belief that the Asserted '191 patent claims are invalid."), *with Commil*, at *6 n.1 ("We ***certainly do not hold*** 'that if the inducer of infringement believes in good faith that the patent is invalid, there can be no liability for induced infringement.' … Nor do we 'include a belief in patent validity as a criterion of infringement.'"). Further, *Commil* is not an ANDA case. Infringement liability for ANDA filers turns on what would happen *after* ANDA approval, *Cephalon, Inc. v. Watson Pharms.*, 629 F. Supp. 2d 338, 350 (D. Del. 2009), and typically proved by the proposed label. *AstraZeneca*, 633 F.3d at 1059-60; *In re Alfuzosin Patent Litig.*, 2010 WL 1956286, at *3 (D. Del. May 14, 2010). If the Court rules for ViiV, Lupin would have no basis in the future for believing the patent is invalid.

that ViiV failed to show its entitlement to a permanent injunction under § 271(e)(4)(B) in those circumstances.[8] Mr. Collier testified as to the irreparable harm that ViiV UK and ViiV Co. would suffer if Lupin were to launch a generic version of Trizivir®. Tr. 839:6-14, 848:22-851:19; *see also Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc.*, 821 F. Supp. 2d 681, 694 (D.N.J. 2011). Lupin's suggestion that "only non-party GSK may lose sales" is wrong. Opp. Br. 19-20. ViiV owns and sells Trizivir®, and no evidence or testimony suggested otherwise. It is well-established that Hatch-Waxman is a balance between (1) inducing innovators such as ViiV to make the necessary investments in new drugs, and (2) enabling generics to bring lower-cost versions of those drugs to market in a timely fashion. Lupin's only response is to assert that public policy favors "eliminating unwarranted patent grants." That consideration does not apply given Lupin's failure to prove invalidity. *Sanofi*, 821 F. Supp. 2d at 695-96 (citing *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005)).

D. LPI Is A Proper Defendant

This Court has held, and the Federal Circuit affirmed, that "liability for infringement may extend to an agent of the applicant who signs the ANDA and intends to benefit directly if the ANDA is approved." *In re Rosuvastatin Patent Litig.*, 719 F. Supp. 2d 388, 396 (D. Del. 2010) (citing cases), *aff'd*, 703 F.3d 511 (Fed. Cir. 2012). Lupin ignores *Rosuvastatin*, ViiV Br. 7, and cites a Pennsylvania case for the proposition that the mere filing of an ANDA is not sufficient for liability under § 271(e)(2). Here, however, LPI is not a mere ministerial filer.[9] Rather, Lupin's ANDA confirms LPI's role in marketing and distributing Lupin's generic product will be sufficient to meet the standard of *Rosuvastatin*. ViiV Br. 6. In short, LPI is a proper defendant.

[8] This point is only relevant if the Court does not grant ViiV relief before the statutory stay expires.

[9] Nor is LPI a mere "mailbox," as Lupin argued at closing and as courts have explicitly rejected. *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 493-94 (E.D. Va. 2005); *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 306-07 (D. Md. 2007).

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